



MOLECULE	PHARMACEUTICAL FORM & STRENGTH	REFERENCE PRODUCT	INDICATION	DOSSIER STATUS
Apixaban	Film-coated tablets 2.5 mg, 5 mg	Eliquis® BMS/Pfizer	Antithrombotic	Approved: ANDA Under preparation: EU
Captopril	Tablets 12.5 mg, 25 mg, 50 mg, 100 mg	Captopril Mylan	Hypertension	Approval Q4'19: ANDA
Daptomycin	Powder for solution for injection or infusion in glass vial 350 mg, 500 mg	Cubicin® Merck	Antibiotic	Approved: AU, CA, EU, UK Filed: KR, ZA
Prucalopride Succinate	Film-coated tablets 1 mg, 2 mg	Resotrans® Janssen Resolor® Shire	Chronic constipation	Filed: EU, UK Under preparation: ANDA
Quetiapine	IR scored tablets New dose 12.5 mg, 25 mg	Seroquel® AstraZeneca	Schizophrenia bipolar disorder	Under preparation: EU
Rivaroxaban	Film-coated tablets 2.5 mg, 10 mg, 15 mg, 20 mg	Xarelto® Bayer	Antithrombotic	Approved: EU Filed: BA, SR
Sodium Oxybate	Oral Solution in bottle 300 mg/ml	Xyrem® UCB Pharma	Narcolepsy	Approved: EU, UK
Sugammadex Sodium	Solution for injection 200 mg / 2 ml 500 mg / 5 ml	Bridion® MSD	Reversal of neuromuscular blockade in anesthesia	Approved: EU Filed: KR, IL, TR Under preparation: ANDA
Sunitinib Malate	Capsules 12.5 mg, 25 mg, 37.5 mg, 50 mg	Sutent® Pfizer	Renal carcinoma, pancreatic and stromal tumors	Approved: EU Filed: LATAM, MENA
Tobramycin	Nebulizer solution in plastic ampoule blow-fill-seal 300 mg / 5 ml	Tobi® Novartis	Cystic fibrosis	Approved: AU, EU, LATAM, NZ, UK Filed: ANDA
Thalidomide	Capsules 50 mg	Thalidomid Celgene® Celgene	Multiple myeloma	Approved: EU, UK

AVAILABLE DOSSIERS

PRODUCT	STRENGTH	INDICATION	FORMATS AVAILABLE
Hydroalcoholic solution Transparent and coloured	2%	Antiseptic preoperative disinfection of the intact skin	Plastic bottles 60 ml, 75 ml, 100 ml, 125 ml, 250 ml, 500 ml More formats on request
	0.50%	Antiseptic	
Aqueous solution	2%	Antiseptic	Blow-fill-seal ampoules and plastic bottles Single dose (10 ml), 60 ml, 75 ml, 100 ml, 125 ml, 250 ml, 500 ml
	0.50%		
Wipes Aqueous	2%	Disinfection of the intact skin Antiseptic	Individual sachet
			Flow pack of 8 wipes
Alcoholic			Individual sachet 20 x 20 cm, 6 x 7 cm
Hand scrub Transparent	4%	Hygienic hand wash Disinfection of the intact skin	Sachet HDPE bottles with dosing pump 20 ml, 500 ml, 1000 ml

AVAILABLE DOSSIERS

PRODUCT	STRENGTH	INDICATION	FORMATS AVAILABLE
Hydroalcoholic solution Transparent	0.50%	Disinfection of the intact skin prior to invasive medical procedures Hygienic and pre-operative hand disinfection	Plastic bottles 30 ml, 100 ml, 250 ml More formats on request



MALTA

Ambrisentan	Micafungin Sodium	○ Solifenacin Succinate
○ Apixaban	Quetiapine Fumarate	○ Sugammadex Sodium
Cinacalcet HCl	○ Rasagiline Tartrate	○ Sunitinib Malate
Dabigatran Etexilate Mesylate	○ Rivaroxaban	Vildagliptin
Desvenlafaxine Succinate	Saxagliptin HCl	Voriconazole
Lorcaserin HCl		

SPAIN

Adapalene	Felodipine	○ Mirtazapine
st Amoxapine	Fluvoxamine Maleate	Nepafenac [sterile and non sterile]
Asenapine Maleate	Guanfacine HCl	Olopatadine HCl
st Brimonidine Tartrate	Lamotrigine	Paroxetine HCl
○ Captopril	Lorcaserin HCl	Pimecrolimus
Clozapine	Loxapine Base	○ Quetiapine Fumarate
Cyclobenzaprine HCl	st Loxapine Succinate	Voriconazole
Desvenlafaxine Base	Methisoprinol [Inosine Pranobex]	
Enalapril Maleate	Mexiletine HCl	

○ Vertically integrated [API / FDF] st USP reference standard

AVAILABLE

Chlorhexidine Base	Chlorhexidine Dihydrochloride	CEP*
Chlorhexidine Digluconate 20% Solution	Octenidine Hydrochloride	DMF* and CEP* expected in 2020
Chlorhexidine Diacetate		

CEP* Certificate of Suitability DMF* Drug Master File

For information on our products under development, please contact us at:
bd@medichem.es
chlorhexidine@medichem.es
www.medichem.es

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